



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/466,921	06/06/95	ALIZON	M 03459.0008-0

HM21/0316

FINNEGAN HENDERSON FARABOW
GARRETT AND DUNNER
1300 I STREET NW
WASHINGTON DC 20005-3315

EXAMINER

PARKIN, J

ART UNIT

1648

PAPER NUMBER

DATE MAILED: 03/16/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/466,921	Applicant(s) Alizon et al.
	Examiner Jeffrey S. Parkin, Ph.D.	Group Art Unit 1648

Responsive to communication(s) filed on 15 Dec 1997

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 28, 29, and 32-45 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) 39-45 is/are allowed.

Claim(s) 28, 29, and 32-38 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of Applicants' response filed 15 December, 1997. Claims 28, 29, and 32-45 are pending in the application.

5

35 U.S.C. § 112, First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15

3. The previous rejection of claims 39-45 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is hereby withdrawn in response to 20 the Declaration of Mme. Danielle Berneman.

20

4. Claims 28, 29, and 32-38 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable 25 any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claimed invention is directed toward HIV-1 DNA restriction fragments. The disclosure provides preliminary restriction maps of LAV cDNA (e.g., pLAV75, pLAV82 and pLAV13) and lambda phage clones (e.g., λJ19 and λJ81) 30 (refer to Figures 1 and 2). The restriction coordinates are disclosed on page 4, as well as a series of restriction fragments

believed to correspond to the *gag*, *pol* and *env* coding regions (e.g., *Pst*I (800 nt)/*Kpn*I (3500 nt); *Kpn*I(3,500 nt)/*Bgl*III (6,500 nt); *Kpn*I (6,100)/*Bgl*III (9150)). The specification does not disclose, *ipsis verbis*, HIV/LAV viral clones or restriction fragments obtained from any other viral isolate.

Applicants traverse and assert that the teachings of Goodenow et al. (1989), Holland et al. (1992), and Gao et al. (1994) were improperly relied upon because they were published after applicants' filing date. Applicants further argue that the disclosure clearly teaches the skilled artisan to determine whether or not they possess the claimed invention. Applicants arguments have been thoroughly considered but are not deemed to be persuasive for the reasons of record in paper no. 15 and as further elaborated below.

Concerning the first aspect of applicants' traversal, although it is generally preferred that the submission of pre-filing date, or effective filing date, references should be provided to support a *prima facie* demonstration of lack of enablement, nonetheless, it is also acceptable to submit later-dated references if they provide evidence as to what was known on or before the effective filing date of the application. Thus, if individuals skilled in the art state that a particular invention is not feasible after the filing date of the claimed invention, that would be sufficient evidence that the invention was not possible at the time of filing. Moreover, the court decided in *In re Budnick*, 190 U.S.P.Q. 422 (C.C.P.A. 1976), that the argument of counsel cannot take the place of evidence. The references relied upon were cited only to demonstrate that HIV-1 exists as a complex group of genotypic and phenotypic variants. Each variant will have a unique nucleotide sequence and varying restriction endonuclease profiles.

Concerning the second aspect of applicants' traversal and contrary to the arguments presented, the disclosure fails to adequately teach

the skilled artisan how to arrive at the instant invention. The claims simply recite a purified HIV-1 restriction fragment. At the effective filing date of the applicants' invention, detailed nucleotide sequence listings and restriction maps were not available.

5 Considering the quasispecies nature of lentiviruses, the skilled artisan, *a priori*, could reasonably assume that variants exist containing nucleotide sequence additions, deletions, and various substitutions. Accordingly, it is not readily manifest how the skilled artisan could make or determine if they were in possession of

10 the claimed invention absent further limitations in the claim language (i.e., a purified HIV-1 DNA fragment generated by a *Bam*HI site at approximately 8150 and a *Bgl*II site at approximately 9150 wherein said fragment is capable of hybridizing to the corresponding λ J19 restriction fragment under conditions of . . .). Therefore, the

15 rejection is maintained.

35 U.S.C. § 112, Second Paragraph

5. Claims 28, 29, and 32-38 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of

20 the subject matter that will be protected by the patent grant.

25

Applicants traverse, citing *in re Morosi* and *in re Wilson*, and assert that the precise location of the claimed restriction sites is not required. Applicants' arguments have been thoroughly considered but are not deemed to be persuasive for the reasons of record in

30 paper no. 15. As previously set forth, the claim language fails to clearly and distinctly set forth the subject matter being claimed. Accordingly, the metes and bounds of the patent protection desired

cannot be ascertained.

Allowable Subject Matter

6. Claims 39-45 appear to be free of the prior art and are allowable.
5 Claims 28 and 29 would also be allowable with appropriate amendment
of the claim language to reflect their dependence upon claims 39-45.

Finality of Office Action

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension
10 of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS
SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE
EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE
OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL
15 AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE
SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY
ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R.
§ 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY
ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE
20 LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

8. The Art Unit location of your application in the Patent and
25 Trademark Office has changed. To facilitate the correlation of
related papers and documents for this application, all future
correspondence should be directed to **art unit 1648**.

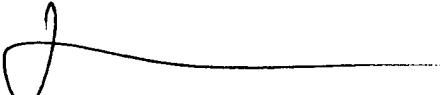
9. Correspondence related to this application may be submitted to
30 Group 1600 by facsimile transmission. The faxing of such papers must
conform with the notice published in the Official Gazette, 1096 OG 30
(November 15, 1989). Official communications should be directed
35 toward one of the following Group 1600 fax numbers: (703) 308-4242 or
(703) 305-3014. Informal communications may be submitted directly to
the Examiner through the following fax number: (703) 305-7401.
Applicants are encouraged to notify the Examiner prior to the

Serial No.: 08/466,921
Applicants: Alizon et al.

submission of such documents to facilitate their expeditious processing and entry.

5 10. Any inquiry concerning this communication should be directed to **Jeffrey S. Parkin, Ph.D.**, whose telephone number is **(703) 308-2227**. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, **Donald E. Adams, Ph.D.**, can be reached at **(703) 308-0570**. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

12 March, 1998


LAURIE SCHEINER
PRIMARY EXAMINER